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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) 001107.00527	
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		First Named Inventor Brad St. Croix, et al.	
		Art Unit 1643	Examiner M. Natarajan
Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request. This request is being filed with a notice of appeal. The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.			
I am the <input type="checkbox"/> applicant/inventor. <input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/95) <input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>32,141</u> <input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____		/Sarah A. Kagan/ Signature Sarah A. Kagan Typed or printed name (202) 824-3000 Telephone number June 30, 2009 Date	
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.			
<input checked="" type="checkbox"/> *Total of <u>1</u> forms are submitted.			

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Brad St. Croix, et al.) Art Unit: 1643
Serial No. 10/519,805) Confirmation No. 7620
Filed: December 13, 2005) Examiner: M. Natarajan
) Atty Docket No.: 001107.00527

For: Secreted and Cytoplasmic Tumor Endothelial Markers

REASONS SUPPORTING PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
Box 1450
Alexandria, VA 22313-1450

Via facsimile—571-273-8300

Sir:

This paper accompanies a Pre-Appeal Brief Request for Review and a Notice of Appeal. Claims 23, 24, 26, 27 are pending and are rejected under 35 U.S.C. § 102(e). There are clear errors in the rejection.

Independent claim 23 is directed to a method of identifying tumor endothelial cells. The method comprises steps of (i) contacting a population of tumor cells containing endothelial cells with one or more antibodies which bind specifically to secreted protein, acidic, cysteine-rich (osteonectin); (ii) detecting cells in the population which have bound to said antibodies; and (iii) identifying cells which are bound to said antibodies as tumor endothelial cells.

Dependent claim 24 further comprises the step of: (iv) isolating cells which have bound to said antibodies. Dependent claims 26 and 27 recite that the population of cells is in a tissue or bodily fluid, respectively.

Each of the pending claims is rejected under 35 U.S.C. § 102(e) as anticipated by Long, US 2004/0214241. The Examiner did not properly apply controlling legal precedent with respect to inherency and did not draw proper logical conclusions based on the facts.

Rejection Under 35 U.S.C. § 102(e)

A reference cited under 35 U.S.C. § 102 must expressly or inherently describe each element set forth in the rejected claim. *Verdegual Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Long does not expressly disclose step (i) of claim 23 (“contacting a population of tumor cells containing endothelial cells with one or more antibodies which bind specifically to secreted protein, acidic, cysteine-rich (osteonection)”). Long teaches contacting a population of cells that includes bone precursor cells (claim 1). Long teaches that this population is obtained from bone marrow cells, bone, or peripheral blood cells (paragraph 0039). Long does not expressly disclose using a population of tumor cells, or such a population containing endothelial cells. The examiner implicitly acknowledges that Long does not expressly teach this population of cells by asserting that Long inherently teaches a method of identifying tumor endothelial cells.

To establish inherency, however, extrinsic evidence “must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.” *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 U.S.P.Q.2d 1746, 1759 (Fed. Cir. 1991) (emphasis added). The Examiner asserts that because Long teaches contacting a population of cells, those cells must be tumor cells if they

bind to the antibody, because the instantly claimed method would identify cells as tumor endothelial cells if they bind to the antibody. This reasoning fails because its underlying logic is faulty.

A population of cells as taught by Long is from bone marrow, bone, or peripheral blood. If these cell types *necessarily* contain tumor cells, as would be required according to *Continental Can*, then 100 % of the human population would have a bone or hematopoietic cancer. In fact, many humans in the population do not have bone or hematopoietic cancers.¹ Therefore, many cell populations from bone or bone marrow or peripheral blood do not contain cancer cells.

The U.S. Patent and Trademark Office has provided no extrinsic evidence to demonstrate that the missing descriptive matter is necessarily present in the thing described in the reference. Common sense and casual observations indicate that the missing descriptive subject matter is not necessarily present in the reference.

The methods of each of Long and the claimed invention starts with a different starting material. Long finds a subset of his starting population and identifies it as being a bone precursor cells. The claimed invention identifies a subset among its different starting population and identifies it as being endothelial cells. The fact that they each allegedly use the same type of

¹ This conclusion accords with our casual observations. In fact, *all* cancers occur with a frequency of 462.9 per 100,000 in the U.S. (All statistics are taken from the SEER Cancer Statistics Review (CSR), a report of cancer incidence, mortality, survival, prevalence, and lifetime risk statistics, is published by the Cancer Statistics Branch of the NCI.) This is 4.6×10^{-1} %, not 100 %. Even if all cancers started in the bone or bone marrow, it is clear that any population of cells from the bone or bone marrow as taught by Long would not necessarily contain cancer cells. The following types of cancers arise out of bone or bone marrow: bone and joint cancers, lymphoma, myeloma, leukemias, lymphocytic cancer, myeloid and myocytic cancers. Bone and joint cancers occur at 0.9 per 100,000, *i.e.*, 9×10^{-3} %. Lymphoma occurs at an incidence of 22.3 per 100,000, *i.e.*, 2.2×10^{-2} %. Myeloma occurs at 5.6 per 100,000, *i.e.*, at 5.6×10^{-3} %. Leukemias occur at 12.2 per 100,000 *i.e.*, 1.2×10^{-2} %. Lymphocytic cancer occur at 6.1 per 100,000, *i.e.*, 6.1×10^{-3} %. Myeloid and myocytic cancers occur at 5.4 per 100,000, *i.e.*, 5.4×10^{-3} %. These percentages do not add up to 100 %. These statistics demonstrate that only a small fraction of bone or bone marrow derived cell populations would contain cancer cells. Therefore any population of cells from the bone or bone marrow as taught by Long would not necessarily contain cancer cells.

antibody to identify the different subsets does not make the two methods the same, nor does it make the two resulting cell subsets the same. This is because they start with two separate and distinct cell populations.

The logic of the rejection is simply faulty. The rejection states that Long's "isolated cells would be identified as 'tumor endothelial cells' (as claimed) because they bound to said antibody."² If tumor endothelial cells are not present in the starting population, however, they will not be found, identified, or enriched by contacting with an antibody. If tumor endothelial cells are not necessarily present in the starting populations of Long, then Long cannot anticipate.

Withdrawal of this rejection is requested because it does not comply with the law of anticipation by inherency.

Respectfully submitted,

BANNER & WITCOFF, LTD.

Date: June 30, 2009

Customer Number: 22907

By: / Sarah A. Kagan/
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² Office Action at page 3, lines 15-17.